

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

MIMEDX GROUP, INC, <i>Plaintiff, Counter-Defendant</i>	§ § § § § § § § § §	v. TISSUE TRANSPLANT TECHNOLOGY LTD. d/b/a BONE BANK ALLOGRAFTS, & TEXAS HUMAN BIOLOGICS, LTD., <i>Defendants, Counter-Plaintiffs.</i>
		NO. 1:14-CV-00464 JURY TRIAL DEMANDED

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

Defendants, Tissue Transplant Technology, Ltd. d/b/a Bone Bank Allografts ("Bone Bank Allografts") and Human Biologics of Texas, Ltd ("THB") file this, their Answer, Affirmative Defenses and Counterclaims to Plaintiff's First Amended Complaint,¹ and allege as follows:

I. ANSWER

Plaintiff's First Amended Complaint is answered in the same numerical order as the numbered paragraphs contained therein.

Nature and Basis of Action

1. Bone Bank Allografts and THB admit this action arises under the patent laws of the United States. The remaining allegations contained in Paragraph No. 1 are denied.

2. Bone Bank Allografts and THB admit Plaintiff seeks relief identified in Paragraph No. 2 but denies Plaintiff is entitled to such relief.

¹ Docket No. 17.

Parties

3. Bone Bank Allografts and THB are without sufficient information to admit or deny the allegations contained in Paragraph No. 3 and therefore deny the same.

4. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 4.

5. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 5.

6. Bone Bank Allografts and THB deny Bone Bank Allografts is a manufacturer of amnion-based allografts. Bone Bank Allografts and THB admit to the remainder of the allegations contained in Paragraph No. 6.

7. Bone Bank Allografts and THB deny THB's legal name is Tissue Human Biologics Ltd. Bone Bank Allografts and THB admit the correct legal name for THB is Human Biologics of Texas, Ltd. and does business as Tissue Human Biologics. Bone Bank Allografts and THB admit the remainder of the allegations contained in Paragraph No. 7.

8. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 8.

9. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 9.

10. Bone Bank Allografts and THB are without sufficient information to admit or deny the allegations contained in Paragraph No. 10 and therefore deny the same.

11. Bone Bank Allografts and THB admit Vivex offers the Cygnus Solo and Cygnus tissue graft products in the United States. Bone Bank Allografts and THB are without sufficient

information to admit or deny the remainder of the allegations contained in Paragraph No. 11 and therefore deny the same.

12. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 12.

13. Bone Bank Allografts denies making the Cygnus Solo and Cygnus products. Bone Bank Allografts and THB admit the remainder of the allegations contained in Paragraph No. 13.

Jurisdiction and Venue

14. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 14.

15. Bone Bank Allografts and THB admit they transact business within the State of Texas, admit this Court has personal jurisdiction and admit placing products into the stream of commerce. Bone Bank Allografts and THB deny the remainder of the allegations contained in Paragraph No. 15.

16. Bone Bank Allografts admits to the allegations contained in Paragraph No. 16. THB is without sufficient information to admit or deny the allegations contained in Paragraph No. 16.

17. THB admits to the allegations contained in Paragraph No. 17. Bone Bank Allografts is without sufficient information to admit or deny the allegations contained in Paragraph No. 17.

18. Bone Bank Allografts and THB admit venue is proper in this Court but seek transfer of this lawsuit to the San Antonio Division pursuant to 28 U.S.C. § 1404(a).

Background

I. MiMedx and Its Products

19. Bone Bank Allografts and THB admit MiMedx offers products processed from placental human amniotic membrane. Bone Bank Allografts and THB are without sufficient information to admit or deny the remainder of the allegations contained in Paragraph No. 19 and therefore deny the same.

20. Bone Bank Allografts and THB admit MiMedx offers the EpiFix and AmnioFix products. Bone Bank Allografts and THB are without sufficient information to admit or deny the remainder of the allegations contained in Paragraph No. 20 and therefore deny the same.

21. Bone Bank Allografts and THB are without sufficient information to admit or deny the allegations contained in Paragraph No. 21 and therefore deny the same.

22. Bone Bank Allografts and THB are without sufficient information to admit or deny the allegations contained in Paragraph No. 22 and therefore deny the same.

II. The Patents-in-Suit

23. Bone Bank Allografts and THB admit MiMedx is identified as the owners of the Patents-in-Suit. Bone Bank Allografts and THB are without sufficient information to admit or deny the remainder of the allegations contained in Paragraph No. 23 and therefore deny the same.

24. Bone Bank Allografts and THB admit that the U.S. Patent and Trademark Office records state on their face that United States Patent No. 8,597,687 (“the ’687 patent”) is entitled “Methods for Determining the Orientation of a Tissue Graft,” was issued on December 3, 2013, and identifies John Daniel as an inventor. Bone Bank Allografts and THB deny the remainder of the allegations contained in Paragraph No. 24.

25. Bone Bank Allografts and THB admit that the U.S. Patent and Trademark Office records state on their face that MiMedx is identified as an assignee of the '687 patent and that Exhibit A purports to be the '687 patent. Bone Bank Allografts and THB deny the remainder of the allegations contained in Paragraph No. 25.

26. Bone Bank Allografts and THB admit that the U.S. Patent and Trademark Office records state on their face that United States Patent No. 8,709,494 ("the '494 patent") is entitled "Placental Tissue Grafts," was issued on April 29, 2014, and identifies John Daniel as an inventor. Bone Bank Allografts and THB deny the remainder of the allegations contained in Paragraph No. 26.

27. Bone Bank Allografts and THB admit that the U.S. Patent and Trademark Office records state on their face that MiMedx is identified as an assignee of the '494 patent and that Exhibit B purports to be the '494 patent. Bone Bank Allografts and THB deny the remainder of the allegations contained in Paragraph No. 27.

III. Infringement of the Patents-in-Suit by Defendants

28. Bone Bank Allografts and THB admit that THB processes tissue into allografts. Bone Bank Allografts and THB deny the remainder of the allegations contained in Paragraph No. 28.

29. Bone Bank Allografts and THB deny the existence of a partnership. Bone Bank Allografts and THB admit the remainder of the allegations contained in Paragraph No. 29.

30. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 30.

31. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 31.

32. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 32.

33. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 33.

34. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 34.

35. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 35.

36. Bone Bank Allografts and THB are without sufficient information to admit or deny the allegation that Vivex markets, sells, and/or offers for sale the Cygnus Solo and Cygnus in this judicial district and therefore deny the same. Bone Bank Allografts and THB admit the remainder of the allegations contained in Paragraph No. 36.

37. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 37.

38. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 38.

39. Bone Bank Allografts and THB admit the allegations contained in Paragraph No. 39.

40. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 40.

41. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 41.

42. Bone Bank Allografts and THB admit Bone Bank Allografts received a letter dated January 24, 2014 that disclosed the '687 Patent.

43. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 43.

44. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 44.

Count I
Infringement of U.S. Patent No. 8,597,687 by THB

45. Bone Bank Allografts and THB repeat and incorporate by reference, as if fully set forth herein, all of their responses to Paragraphs 1 through 44 of the First Amended Complaint.

46. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 46.

47. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 47.

48. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 48.

49. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 49.

50. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 50.

51. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 51.

Count II
Infringement of U.S. Patent No. 8,597,687 by Bone Bank

52. Bone Bank Allografts and THB repeat and incorporate by reference, as if fully set forth herein, all of their responses to Paragraphs 1 through 51 of the First Amended Complaint.

53. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 53.

54. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 54.

55. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 55.

56. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 56.

57. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 57.

58. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 58.

59. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts admits receiving a letter dated January 24, 2014 that disclosed the '687 Patent. Bone Bank Allografts denies the remainder of the allegations contained in Paragraph No. 59.

Count III
Infringement of U.S. Patent No. 8,709,494 by THB

60. Bone Bank Allografts and THB repeat and incorporate by reference, as if fully set forth herein, all of their responses to Paragraphs 1 through 59 of the First Amended Complaint.

61. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 61.

62. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 62.

63. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 63.

64. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 64.

65. No response is required from Bone Bank Allografts as the allegations are directed to THB. THB denies the allegations contained in Paragraph No. 65.

66. Bone Bank Allografts and THB deny the allegations contained in Paragraph No. 66.

Count IV
Infringement of U.S. Patent No. 8,709,494 by Bone Bank Allografts

67. Bone Bank Allografts and THB repeat and incorporate by reference, as if fully set forth herein, all of their responses to Paragraphs 1 through 66 of the First Amended Complaint.

68. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 68.

69. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 69.

70. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 70.

71. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 71.

72. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 72.

73. No response is required from THB as the allegations are directed to Bone Bank Allografts. Bone Bank Allografts denies the allegations contained in Paragraph No. 73.

Prayer for Relief

Bone Bank Allografts and THB deny Plaintiff is entitled to any the relief requested in the Prayer for Relief.

AFFIRMATIVE DEFENSES

Further Answering the First Amended Complaint, Bone Bank Allografts and THB assert the following defenses. Bone Bank Allografts and THB specifically reserve the right to amend its Answer to allege any additional affirmative defenses as they become known through the course of discovery.

1. Bone Bank Allografts and THB have not directly infringed and do not infringe, directly, contributorily or by inducement, willfully or otherwise, any valid claim of the '687 patent under 35 U.S.C. § 271 and is not liable for any acts of infringement of the '687 patent.

2. Bone Bank Allografts and THB have not directly infringed and do not infringe, directly, contributorily or by inducement, willfully or otherwise, any valid claim of the '494 patent under 35 U.S.C. § 271 and is not liable for any acts of infringement of the '494 patent.

3. At least one claim of the '687 patent is invalid, void, and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and 112, and/or under the doctrine of obviousness-type double patenting.

4. At least one claim of the '494 patent is invalid, void, and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and 112, and/or under the doctrine of obviousness-type double patenting.

5. Plaintiff is estopped, based on statements, representations, and admissions made during the prosecution of the patent application resulting in the '687 patent and/or any related patents and applications, from asserting any construction of any of the claims of the '687 patent that contradicts or is inconsistent with arguments made during prosecution of the patent application resulting in the '687 patent and/or any related patents and applications.

6. Plaintiff is estopped, based on statements, representations, and admissions made during the prosecution of the patent application resulting in the '494 patent and/or any related patents and applications, from asserting any construction of any of the claims of the '494 patent that contradicts or is inconsistent with arguments made during prosecution of the patent application resulting in the '494 patent and/or any related patents and applications.

7. The '494 patent is invalid, void, and/or unenforceable for failure to comply with inventorship requirements.

DEFENDANTS' COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Defendants and Counter-Plaintiffs Tissue Transplant Technology, Ltd. d/b/a Bone Bank Allografts ("Bone Bank Allografts") and Human Biologics of Texas, Ltd ("THB"), by way of Counterclaims against Plaintiff and Counter-Defendant MiMedx Group, Inc. ("MiMedx"), allege as follows:

Nature and Basis of Action

1. This is an action for declaratory judgment for non-infringement and invalidity with respect to U.S. Pat. No. 8,597,687 ("the '687 patent") and U.S. Pat. No. 8,709,494 ("the '494 patent").

Parties

2. Counter-Plaintiff Bone Bank Allografts is a limited partnership organized under the laws of the State of Texas and maintains its principal place of business at 4808 Research, San Antonio, Texas 78240.

3. Counter-Plaintiff THB limited partnership organized under the laws of the State of Texas and maintains its principal place of business at 14805 Omicron Drive, San Antonio, Texas 78245.

4. Counter-Defendant MiMedx is a corporation organized and existing under the laws of the State of Florida and maintains its headquarters and principal place of business at 1775 West Oak Commons Ct., Marietta, Georgia 30062.

Jurisdiction and Venue

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a) and 2202. This Court has personal jurisdiction over MiMedx as MiMedx has availed itself to the jurisdiction of this Court by filing the above-styled lawsuit in this District.

6. Venue is proper in this District as MiMedx is asserting infringement of the '687 patent and the '494 patent against Counter-Plaintiffs in this Court. Venue is more convenient in the San Antonio Division of the Western District of Texas as Counter-Plaintiffs have argued in a separate motion. These counterclaims should be transferred along with the Plaintiff's claims to the San Antonio Division of the Western District of Texas pursuant to 28 U.S.C. § 1404(a).

Background

7. MiMedx alleges Counter-Plaintiffs previously and are currently infringing the '687 patent and the '494 patent through the manufacture, use, selling, and/or offering for sale of the SteriShield I and II products which form the basis of Plaintiff's First Amended Complaint.

8. Adam McQueen began employment with Bone Bank Allografts on February 18, 2013 as the Vice President of Sales.

9. McQueen signed a "Confidentiality, Non-Disclosure and Non-Competition Agreement" with Bone Bank Allografts on February 20, 2013.

10. While employed with Bone Bank Allografts, McQueen participated in confidential conversations regarding the development of the SteriShield II. These confidential conversations included confidential discussions regarding the development and processing of amnion tissue including specific attributes and cellular/histological properties of the SteriShield II product.

11. McQueen ceased employment with Bone Bank Allografts on June 7, 2013.

12. McQueen was hired by MiMedx in May of 2013 as Director of Product Development.

13. Based on information and belief McQueen disclosed confidential discussions regarding the specific attributes and cellular/histological properties of the SteriShield II product.

14. The application that issued as the '494 patent was filed as continuation of U.S. Patent Application No. 13/569,095, filed on August 7, 2012, entitled "Methods for Determining the Orientation of a Tissue Graft," which is a continuation of U.S. Patent Application No. 11/840,728, filed on August 17, 2007, now U.S. Patent No. 8,372,437, which claims the benefit under 35 U.S.C. § 119(e) of U.S. provisional patent application No. 60/838,467, entitled "Method and System for Preserving Amnion Tissue For Later Transplant," filed August 17, 2006.

15. At least one or more claims of the '494 patent were submitted to the United States Patent and Trademark Office after McQueen began employment with MiMedx.

16. At least one or more claims of the '494 patent do not have any supporting disclosure in the application of the '494 patent as filed on July 30, 2013.

17. At least one or more claims of the '494 patent do not have any supporting disclosure in the specifications of U.S. Patent Application No. 13/569,095, U.S. Patent Application No. 11/840,728, U.S. Patent No. 8,372,437, and U.S. provisional patent application No. 60/838,467.

COUNTERCLAIM I DECLARATORY JUDGMENT OF NON-INFRINGEMENT

18. There exists an actual controversy between the parties as to the alleged infringement of the '687 patent by Counter-Plaintiff's SteriShield I product.

19. Counter-Plaintiffs have not infringed and do not infringe, directly or indirectly, any valid claim of the '687 patent, either literally or under the doctrine of equivalents.

20. There exists an actual controversy between the parties as to the alleged infringement of the '494 patent by Counter-Plaintiff's SteriShield II product.

21. Counter-Plaintiffs have not infringed and do not infringe, directly or indirectly, any valid claim of the '494 patent, either literally or under the doctrine of equivalents.

22. A judicial declaration is necessary and appropriate so that Counter-Plaintiffs may ascertain its rights, and the consequent rights of its customers, suppliers, manufacturers, distributors, resellers, and end users of its products, with respect to the '494 patent and '687 patent.

COUNTERCLAIM II DECLARATORY JUDGMENT OF INVALIDITY

23. There exists an actual controversy between the parties as to the validity of the '687 patent with respect to which Counterclaim Plaintiffs requests a declaratory judgment that the '687 patent is invalid for failing to satisfy at least one of 35 U.S.C. §§ 101, 102, 103, 112, and/or applicable case law.

24. There exists an actual controversy between the parties as to the validity of the '494 patent with respect to which Counterclaim Plaintiffs requests a declaratory judgment that the '494 patent is invalid for failing to satisfy at least one of 35 U.S.C. §§ 101, 102, 103, 112, and/or applicable case law.

25. A judicial declaration is necessary and appropriate so that Counter-Plaintiffs may ascertain its rights, and the consequent rights of its customers, suppliers, manufacturers, distributors, resellers, and end users of its products, with respect to the '494 patent and '687 patent.

JURY DEMAND

Tissue Transplant Technology, Ltd and Human Biologics of Texas, Ltd. hereby demand trial by jury on all issues triable to a jury.

PRAYER

WHEREFORE, Tissue Transplant Technology, Ltd and Human Biologics of Texas, Ltd. respectfully requests that the Court enter judgment in favor of Tissue Transplant Technology, Ltd. and Human Biologics of Texas, Ltd. granting the following relief:

- a) A declaration that Tissue Transplant Technology, Ltd and Human Biologics of Texas, Ltd. have not infringed and do not infringe any valid claim of the '687 patent;
- b) A declaration that Tissue Transplant Technology, Ltd and Human Biologics of Texas, Ltd. have not infringed and do not infringe any valid claim of the '494 patent;
- c) A declaration that all claims of the '687 patent are invalid for failure to meet the conditions of patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 100 et seq. 101, 102, 103, and/or 112, and applicable case law;
- d) A declaration that all claims of the '494 patent are invalid for failure to meet the conditions of patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 100 et seq. 101, 102, 103, and/or 112, and applicable case law;
- e) An injunction against MiMedx and its officers, agents, servants, employees, attorneys, and others in active concert or participation with any of them from asserting infringement or instituting or continuing any legal action for infringement of the '687 patent against Counter-Plaintiffs or its customers, suppliers, manufacturers, distributors, resellers, or end users of its products;
- f) An injunction against MiMedx and its officers, agents, servants, employees, attorneys, and others in active concert or participation with any of them from asserting infringement or instituting or continuing any legal action for infringement of the '494 patent against Counter-Plaintiffs or its customers, suppliers, manufacturers, distributors, resellers, or end users of its products;
- g) An order declaring that this is an exceptional case and awarding Counter-Plaintiffs its costs, expenses, disbursements and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes, rules and common law; and
- h) Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

GUNN, LEE & CAVE, P.C.

/s/ Robert L. McRae

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**ATTORNEYS FOR DEFENDANTS TISSUE
TRANSPLANT TECHNOLOGY, LTD AND
HUMAN BIOLOGICS OF TEXAS, LTD.**

CERTIFICATE OF SERVICE

I hereby certify that on July 10, 2014 I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following:

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